

WHAT IS CLAIMED IS:

1. A stable lansoprazole compound, further comprising greater than 500 ppm and not more than about 3,000 ppm water.
2. The stable lansoprazole compound of claim 1, wherein the stable lansoprazole  
5 compound comprises greater than about 600 ppm and not more than about 3,000 ppm water.
3. A stable lansoprazole compound, further comprising greater than 200 ppm and not more than about 5,000 ppm alcohol.
4. The stable lansoprazole compound of claim 3, wherein the stable lansoprazole  
10 compound comprises greater than about 300 ppm and not more than about 5,000 ppm alcohol.
5. A stable lansoprazole compound, further comprising greater than 500 ppm and not more than about 3,000 ppm water, and greater than 200 ppm and not more than about 5,000 alcohol.
- 15 6. The stable lansoprazole compound as in one of claims 1 to 5, further comprising less than about 0.1% (wt/wt) sulfone derivative and less than about 0.1% (wt/wt) sulfide derivative.
7. The stable lansoprazole compound as in one of claims 1 to 5, wherein the  
20 lansoprazole compound is stable under 2-8<sup>0</sup>C or 25<sup>0</sup>C at a relative humidity of up to 60% for a time period of up to about 6 months.
8. A method of preparing a stable lansoprazole compound, comprising the steps of:
  - a) crystallizing a lansoprazole from an organic solvent or a mixture of organic solvent and water in the presence of an amine; and
  - b) isolating a stable lansoprazole compound,  
25 wherein the stable lansoprazole compound comprises greater than 500 ppm and not more than about 3,000 ppm water.
9. The method of claim 8, wherein the stable lansoprazole compound comprises greater than about 600 ppm and not more than about 3,000 ppm water.
10. A method of preparing a stable lansoprazole compound, comprising the steps of:  
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  - a) crystallizing a lansoprazole from an organic solvent or a mixture of organic solvent and water in the presence of an amine; and
  - b) isolating a stable lansoprazole compound,

wherein the stable lansoprazole comprises greater than 200 ppm and not more than about 5,000 ppm alcohol.

11. The method of claim 10, wherein the stable lansoprazole compound comprises greater than about 300 ppm and not more than about 5,000 ppm alcohol.

5 12. A method of preparing a stable lansoprazole compound, comprising the steps of:

a) crystallizing a lansoprazole from an organic solvent or a mixture of organic solvent and water in the presence of an amine; and

b) isolating a stable lansoprazole compound,

10 wherein the stable lansoprazole compound comprises greater than 500 ppm and not more than about 3,000 water, and greater than 200 ppm, and not more than about 5,000 ppm alcohol.

13. The method as in any one of claims 8 to 12, wherein the organic solvent is at least one solvent selected from the group consisting of ethanol, methanol, n-propanol, i-propanol, dimethyl-carbonate, diethyl-carbonate, acetone, 2-butanone, dimethyl-  
15 formamide and tetrahydrofuran.

14. The method as in any one of claims 8 to 12, wherein the organic solvent is ethanol.

15. The method as in any one of claims 8 to 12, wherein the amine at least one compound selected from the group consisting of ammonia, ammonium hydroxide, diethylamine, triethylamine, methylamine, diethanolamine, and triethanolamine.

20 16. The method as in any one of claims 8 to 12, wherein the amine is ammonium hydroxide.

17. The method of claim 16, wherein the ammonium hydroxide is present at a mol/mol ratio to lansoprazole of about 7 to about 1.

18. The method of claim 17, wherein the ammonium hydroxide is present at a mol/mol  
25 ratio to lansoprazole of greater than about 1.

19. The method as in any one of claims 8 to 12, wherein the crystallizing step is achieved by acidifying the lansoprazole solution with an acid.

20. The method of claim 19, wherein the acid is at least one acid selected from the group consisting of acetic acid, formic acid, and hydrochloric acid.

30 21. The method of claim 19, wherein the acid is acetic acid.

22. The method as in any one of claims 8 to 12, wherein the stable lansoprazole compound further comprises less than about 0.1% (wt/wt) sulfone derivative and less than about 0.1% (wt/wt) sulfide derivative.

23. A method of purifying a lansoprazole compound, comprising the steps of:
- a) crystallizing a lansoprazole from an organic solvent or a mixture of organic solvent and water in the presence of an amine; and
  - b) isolating a crystallized lansoprazole compound,
- 5 wherein the crystallized lansoprazole compound comprises less than about 0.1% (wt/wt) sulfone derivative and less than about 0.1% sulfide derivative (wt/wt) sulfide derivative.
24. The method of claim 23, after step a), further comprising the step of washing the crystallized lansoprazole compound in an acetone-water mixture.
- 10 25. The method of claim 24, wherein the acetone-water mixture is adjusted to a pH of about 8 to about 10.
26. The method of claim 24, wherein the acetone-water mixture is adjusted to a pH of about 9.
27. The method of claim 23, wherein the isolating step comprises drying the crystallized lansoprazole compound in the presence of a weakly basic gas.
- 15 28. The method of claim 27, wherein the weakly basic gas is ammonia or methylamine.
29. A pharmaceutical composition comprising a stable lansoprazole compound and a pharmaceutically acceptable excipient, wherein the stable lansoprazole compound further comprises greater than 500 ppm and not more than about 3,000 ppm water.
- 20 30. The pharmaceutical composition of claim 29, wherein the stable lansoprazole compound comprises greater than about 600 ppm and not more than about 3,000 water.
31. A pharmaceutical composition comprising a stable lansoprazole compound and a pharmaceutically acceptable excipient, wherein the stable lansoprazole compound further comprises greater than 200 ppm and not more than about 5,000 ppm alcohol.
- 25 32. The pharmaceutical composition of claim 31, wherein the stable lansoprazole comprises greater than about 300 ppm and not more than about 5,000 ppm alcohol.
- 30 33. A pharmaceutical composition comprising a stable lansoprazole compound and a pharmaceutically acceptable excipient, wherein the stable lansoprazole compound

further comprises greater than 500 ppm and not more than about 3,000 ppm water and greater than 200 ppm and not more than about 5,000 ppm alcohol.

34. The pharmaceutical composition as in any one of claims 29 to 33, wherein the stable lansoprazole compound further comprises less than about 0.1% (wt/wt) sulfone derivative and less than about 0.1% (wt/wt) sulfide derivative.
35. The pharmaceutical composition as in any one of claims 29 to 33, wherein the pharmaceutical composition is in a dosage form selected from the group consisting of tablets, powders, capsules, suppositories, sachets, troches, lozenges, liquid syrups, suspensions and elixirs.
36. The pharmaceutical composition as in any one of claims 29 to 33, wherein the pharmaceutical composition is a tablet.
37. The pharmaceutical composition as in any one of claims 29 to 33, wherein the pharmaceutical composition comprises lansoprazole in a dosage level of from about 50 to about 300 mg.
38. The pharmaceutical composition as in any one of claims 29 to 33, wherein the pharmaceutical composition comprises lansoprazole in a dosage level of about 200 mg.